Pilot cluster randomised trial of an evidence based intervention to reduce avoidable hospital admissions in residents in care homes (the Better Health in Residents in Care Homes study)

PROTOCOL

Long title of the study	Pilot cluster randomised trial of an evidence based intervention to reduce avoidable hospital admissions in residents in care homes (the Better Health in Residents in Care Homes study)
Short title of study	BHiRCH Pilot cluster randomised trial
Version and date of protocol	Final Version 3 11.10.2017
Sponsor	UCL
Sponsor protocol number	17/0142
Funder (s)	NIHR RP-PG-0612-20010
Study registration number	
IRAS number	220121
Phase of study	Pilot trial
Sites	8 Sites in Yorkshire, and 6 in Greater London
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Sponsor Representative:	Hannah Charles

SIGNATURES

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles of GCP the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator: Dr Elizabeth Sampson

Sign: E Sampson

Date: 12.10.2017

Sponsor Representative: Hannah Charles

Sign:

Date: 16.10.2017

This Protocol template is intended for use with UK sites only.

VERSION HISTORY

Version number	Version date	Reason for Change
Draft 1	24/11/16	Learning from feasibility study
Draft 2	23/02/17	Priment feedback
Draft 3	02/05/17	Programme Steering Committee and Pharmacovigilance
Final	25/05/17	JRO Feedback and QA checks
2	27/07/2017	Revisions following Newcastle REC
3	11/10/2017	Revisions following Queen Square REC

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2 LIST OF ABBREVIATIONS

Commonly used abbreviations – add or delete as applicable.

Term	Definition
ACS	Ambulatory Care Sensitive Conditions
APR	Annual Progress Report
AR	Adverse Reaction
BHiRCH	Better Health in Residents in Care homes
CI	Chief Investigator
CRF	Case Report Form
Non-CTIMP	Clinical Trials without an Investigational Medicinal Product
EudraCT	European Clinical Trials Database
EQ-5D	EuroQuol
GCP	Good Clinical Practice
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
PARiHS	Promoting Action in Research implementation in Health Services
PDC	Practice Development Champion
PDG	Programme Development Grant
PI	Principal Investigator
PM	Programme Manager
RA	Research Associate
REC	Research Ethics Committee
RT	Research staff team
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Document Verification

SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMG	Trial Management Group
UCL	University College London

3 STUDY PERSONNEL

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Members of the research team will be referred to by their initials within the protocol.

4 SUMMARY

Title:	Pilot cluster randomised trial of an evidence based intervention to reduce avoidable hospital admissions in residents in care homes (the Better Health in Residents in Care Homes study)
Short title:	Pilot cluster randomised trial
Phase of study:	Phase II
Objectives:	**Primary:** The purpose of this study is to indicate whether a further definitive study is warranted. **Secondary:** 1. Establish whether resident consent procedures allow the collection of sufficient individual level data; 2. Assess the effectiveness of the implementation strategy; 3. Assess fidelity to the intervention; 4. Assess the level of nursing home staff engagement with the intervention; 5. Investigate whether the intervention would be sustainable outside the context of a trial; 6. Assess potential primary and secondary outcomes for a definitive trial: 7. To collect cost and outcome data for use in an economic evaluation; 8. Estimate the probability that the intervention is cost-effective; 9. Establish the key cost components through economic analysis and the expected value of perfect information (EVPI); 10. Measure the completeness of data collection, completion of documentation and return rate of questionnaires.
Type of study:	Pilot trial
Study design and methods:	**Pilot trial in 14 private care homes, 8 in Yorkshire and 6 in Greater London.** We will conduct a cluster randomised trial in nursing homes. This intervention acts upon a group of people (the nursing home staff who work with residents and their family carers) and thus the nursing home will be the unit of intervention, allocation and analysis. Prior to this work stream we conducted a feasibility study (REC reference 16/LO/1361) with the aim to refine study procedures in 2 care homes in Bradford in preparation for the pilot cluster randomised study. The Better Health in Residents in Care Homes (BHiRCH) intervention aims to reduce rates of hospital admissions from care homes (with nursing) for respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure by ensuring early detection of and early intervention. The BHiRCH programme is a complex intervention, with 4 key components. These are: 1. *Stop and Watch* Early Warning Tool (Appendix C). This form highlights simple signs and behaviours which identify common but non-specific changes in the resident, which is used as an alert to determine whether further assessment is necessary. 2. *Care Pathway* (Appendix D). This form is a clinical guidance and decision support system designed to facilitate early assessment and diagnosis of acute changes in health to prompt early intervention. 3. Structured method for communicating with primary care (SBAR, Appendix E). This communication tool is designed to contribute to appropriate action and increase resident safety. 4. Implementation support- practice development champions and support groups.

	Family members and friends of the resident (referred to as care partners henceforth) may also be involved by reporting changes or concerns about the residents' health. Care partners may also educate/train/inform care staff about how to notice changes in their relatives health. **To achieve the primary and secondary objectives (above) we will collect data in four key domains:** 1) Individual level data on care home residents and staff (where consent or agreement to participate in this has been gained)-see table 1 (below) 2) Process data 3) System-level data 4) Economic evaluation: We will assess the feasibility collecting data and of calculating the quality adjusted life years (QALYs) for residents in the intervention using the EQ-5D to calculate QALYs. There will be 8 Care Homes in Yorkshire; 4 randomised to intervention and 4 to "usual care", and 6 in Greater London; 3 randomised to intervention and 3 to "usual care". Thus there are 14 Homes in total, randomised 1:1 between intervention and "usual care", stratified by location. Randomisation will be undertaken by an independent statistician from the CTU using a statistical programme called SAS. All homes will be randomised at the same time, just prior to the intervention starting. Blinding in this type of study may not be feasible for the research staff collecting the data, as the outcome measures will be different depending on intervention allocation. Data will be analysed by the statisticians and health economists blind to allocation.
Study duration per participant:	3-months recruiting, consenting activities and pre-intervention data collection, 12-months for intervention, 1-month post-intervention data collection. 16-months in total.
Estimated total study duration:	16 months.
Planned study sites:	8 sites in Yorkshire and 6 in Greater London
Total number of participants planned:	All eligible residents will be approached, and their associated care partners in the 14 care homes. All staff in the 14 participating care homes will be approached to take part.
Main inclusion/exclusion criteria:	All residents (or their care partner or other consultees if the resident lacks capacity to consent to participate in research) will be asked whether they wish to participate in the individual-level data collection, other than those who are receiving end of life treatment or palliative care.
Statistical methodology and analysis:	PRIMENT will conduct the analyses. We shall follow CONSORT guidelines for the reporting of randomised trials however, given that this is a pilot study, our analysis will be mainly descriptive and will focus on the recruitment, participant characteristics, other baseline and outcome variables, loss to follow-up and any adverse events. We shall provide a descriptive analysis of all the data (including the completeness of data collection) and compare rates of hospital admission for ACS conditions and other important outcomes between the control and intervention groups through the calculation of confidence intervals.
Data to be collected	**To achieve the primary and secondary aims (above) we will collect data in four key domains:** 1) Individual level data on care home residents, staff and care partners (where consent or agreement to participate in this has been gained)-see table 1 (below) 2) Process data 3) System- level data 4) Economic evaluation data The research team will be collecting the data from the care home records and via speaking with participants (residents, care partners, care home staff) directly and completing questionnaires.

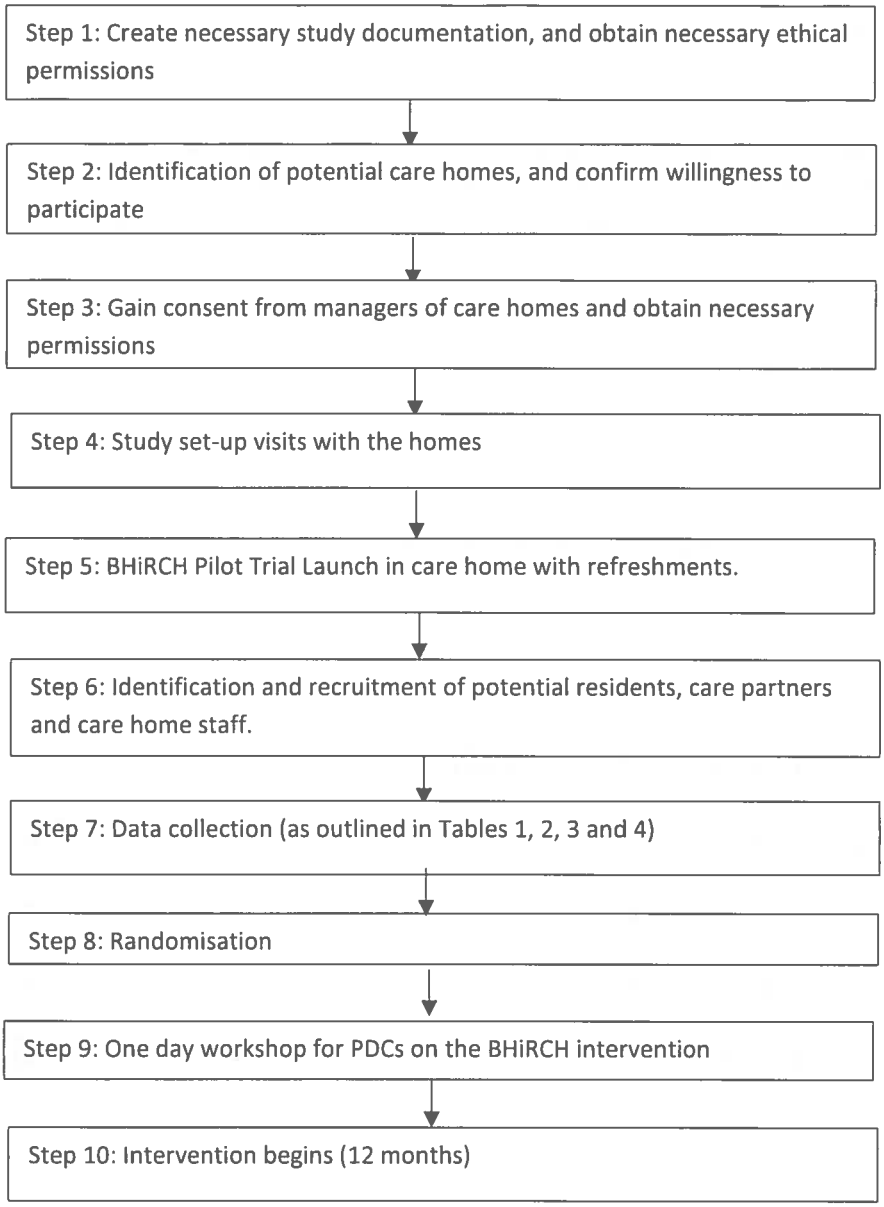
Table 1 Summary of individual-level data collection (residents and staff) and care home data		
	Collected by whom	***How will data be collected?***
Care home		
Care home characteristics	RT	Care home manager
Resource use and cost (training materials, and intervention costs)	RT	RT
Resident		
Resident quality of life using the EQ-5D-5l EuroQol (1990)	RT	Resident
Staff		
Staff demographics	RT	Staff
Degree of perceived organizational support for providing person-centered care (P-Cat; Edvardsson et al., 2010)	RT	Care home staff
Functional ability of residents assessed by Barthel Index (Mahoney & Barthel, 1965)	RT	Proxy rating by staff member or care home records
Nurse ratings of communication with primary care (Tjia et al.,2009)	RT	Care home Nurses
Perceived knowledge and skills for early detection in changes in health	RT	Care home Nurses
Care partner		
Care partner demographics	RT	Care partner
Carer quality of life using the EQ-5D-5L EuroQol (1990)	RT	Care partner
Carer perceived quality of life of the resident EQ-5D-5L Proxy EuroQol (1990)	RT	Care partner/staff
Identify preferred role of care partner	RT	Care partner
Research Team		
Resident demographics	RT	Care home records
Medical consumables such as prescription medication and prosthetics	RT	Care home records
Use of other health and social care services (CSRI)	RT	Care home records and staff

Table 2 Summary of process data collection		
	Collected by whom?	**How will data be collected?**
Use of the early warning tool and care pathway		
Research Team		
The number of completed Stop & Watch Early Warning Tool forms during the intervention, including information regarding dates and times. Include breakdown for how many completed during each shift.	RT	Care pathway documentation
Summary of which changes were circled on the Stop & Watch Early Warning Tool forms.	RT	Care pathway documentation
Who prompted the form to be completed (care assistant, nurse, domestic staff, resident, other staff member, family member, friend) who completed the form (care assistant or nurse) referred/noticed the change on the Stop & Watch Early Warning Tool forms.	RT	Care pathway documentation
The number of forms where no changes were noted after using the Stop & Watch Early Warning Tool form.	RT	Care pathway documentation
The number of Stop & Watch Early Warning Tool forms which resulted in a care pathway being actioned and completed by the nurse.	RT	Care pathway documentation
The number of care pathways which were completed by the nurse who was initially informed when a change was noticed ('reported to- nurses name) in comparison to another nurse completing the care pathway.	RT	Care pathway documentation
The number of primary assessments conducted using the care pathway.	RT	Care pathway documentation
The number of secondary assessments conducted using the care pathway.	RT	Care pathway documentation
The number of primary and secondary assessments using the care pathway which resulted in an ambiguous outcome.	RT	Care pathway documentation
The number of care pathways administered 6-hours later if primary and/or secondary assessments using the care pathway resulted in an ambiguous outcome	RT	Care pathway documentation
Outcomes of care pathway assessment: Further general monitoring using the stop and watch tool Monitoring for specific symptoms Treatment initiated in care home Condition communicated with primary care (occasions & with whom)	RT	Care pathway documentation
Changes or amendments to the structure or content of the care pathway documents will be noted.	RT	Care pathway documentation

Table 2 Summary of process data collection (continued)		
	Collected by whom?	**How will data be collected?**
Implementation of the early warning tool and care pathway		
Staff		
Experience of implementing and receiving the intervention and its effectiveness.	RT	Qualitative interviews with nursing home managers, nurses, care assistants, care partners.
Research Team		
Modifications made to the intervention and implementation support.	RT	CRFs
Practice Development Champions & Practice Development Support Group Members' Time spent implementing intervention.	RT	CRFs
Researcher will keep detailed field notes of monthly support calls with Practice Development Champions	RT	RT- field notes
Collection of system-related data		
Research Team		
Number of residents and care partners who are approached to participate in the study and % who give consent or agreement is obtained from family	RT	Researcher records
Number of friends, family members or care partners wishing to be involved in their relative's health care and in what aspects	RT	Care home records
Completeness of data collection on outcome measures	RT	CRFs

Table 3 Summary of system-level data collection		
Item to be measured by research team	*Collected by whom*	*How will data be collected ?*
Number of acute hospital admissions from respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure	RT	Care home records
Structured Implicit Record Review (SIRR; Saliba et al., 2000) tool, care home records and healthcare notes to assess whether admissions were avoidable.	Clinician	Care home records
Care pathway *Primary assessment* How many indicated for lower respiratory infection, urinary tract infections, dehydration, congestive heart failure? *Secondary assessment* How many indicated lower respiratory infection, urinary tract infections, dehydration, congestive heart failure?	RT	Care pathway documentation
Number of hospital admissions, A&E attendances and readmissions	RT	Care home manager
Number of ambulances called	RT	Care home manager
Staff turnover	RT	Care home manager
Unscheduled (out of hours) GP visits or telephone contact	RT	Care home manager
Accident and Emergency attendance	RT	Care home manager
Number of available beds to new residents	RT	Care home manager
Length of residents' hospital admissions	RT	Care home manager
Deaths in the last calendar month	RT	Care home manager

Figure 1. Pilot trial Flow Chart



5 INTRODUCTION

5.1 BACKGROUND

The problem being addressed: Early detection and intervention for ill health in residents in care homes is problematic. People living in care homes may be admitted to hospital for conditions which, if noticed and treated earlier, could have been managed in the care home. In the context of this research when we say 'care home' we refer to care home with nursing.

The aim of this intervention: The NIHR funded Better Health in Residents in Care Homes (BHiRCH) programme aims to reduce rates of hospital admissions from care homes for respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure by ensuring early detection and early intervention of these conditions. Early detection and active management of these conditions has the potential to prevent an acute deterioration in health leading to an emergency presentation to hospital. This project is specifically focused on these four conditions as they are collectively responsible for a large proportion of unplanned hospitalisations.

The way it was developed: This programme incorporates what we know from the literature and practice about effective approaches to ensuring early detection and intervention. It takes into account the multiple perspectives of several key stakeholders – family members, close friends or care partners of residents in care homes, health and social care staff, care home managers, other care professionals, and our research team. Consensus among these key stakeholders has been reached during a series of three workshops.

Key components of the programme:

1. Early Warning Tool (*Stop and Watch* Early Warning Tool).
2. *Care Pathway* (clinical guidance and decision support system).
3. Structured method for communicating with primary care.
4. Implementation support via local practice development champions and each care home's practice development group

5.2 PRECLINICAL DATA

The programme development grant (PDG) systematic literature review confirmed the paucity of research in this area in the UK and across Europe. Multi-component interventions for reducing rates of avoidable hospitalisations have only been evaluated in US care homes, where there are some indications that these are effective.

Active management of healthcare and reducing rates of hospitalisation from care homes needs to be seen within the broader context of the drive to improve the quality of care in care homes. Several key recent policy documents include the National Dementia Strategy (Department of Health, 2009), the National Audit Office (2007, 2010) and the House of Commons Committee of Public Accounts (2008, 2010). It is a priority for the National Quality Board and the National Commissioning Board. The UK Care Quality Commission has raised consistent concerns about the quality of care in care homes and an All Party Parliamentary Group (APPG) has just launched a report on dementia and comorbidities.

Despite the policy imperative to reduce avoidable hospital admissions (Department of Health, 2012) and concerns raised by the King's Fund (2012), the British Geriatrics Society (2012), a joint working party from the Royal College of Physicians, Royal College of Nursing and the British Geriatrics Society (2011) about healthcare provision to the care home sector, little empirical research has been conducted to ensure proactive healthcare in UK care homes. Furthermore, the quality of intervention studies which have been conducted is highly variable. Insufficient attention was paid to key methodological issues, particularly issues of implementation, adherence to the intervention or the clustering effect within care homes. There is a lack of robustly conducted randomised controlled studies.

5.3 CLINICAL DATA

The PDG systematic literature review found that respiratory infections, urinary tract infections, dehydration, and acute exacerbation of chronic heart failure were collectively responsible for a large proportion of unplanned hospital admissions. Promising multi-component interventions focused on a) enhancing knowledge and skills of care home staff; b) clinical guidance and decision-support tools (care pathways); c) engaging with families; and d) implementation support. The highest quality studies focused on interventions which require additional specialist input from geriatricians or nurse practitioners.

INTERACT (Ouslander et al., 2011) is an existing intervention, identified in our systematic literature review. INTERACT is a quality improvement program that focuses on the management of acute changes in a resident's condition. It includes clinical and educational tools and strategies for use in everyday practice in long-term care facilities. Effective implementation of this intervention has been associated with substantial reductions in hospitalization of care home residents. The current program and Version 4.0 Tools are publicly (and freely) available for clinical use on the INTERACT website. We have developed clinical guidance and decision making tools (care pathways) for use in the UK informed by existing pathways in use, such as INTERACT, in acute care settings nationally and in care home settings internationally such as the 'Interventions to Reduce Acute Care Transfers (INTERACT)' study.

6 RATIONALE AND RISKS/BENEFITS

The primary aim of this is pilot trial is to indicate whether a definitive study is warranted. Pilot trial procedures have been optimised following the feasibility study. Our intervention is an enhancement of usual clinical care and in fact, similar to "Vanguard" projects are being rolled out across the UK. In our study we will pay close attention to the potential risks of the implementation of the intervention across the care home and our process data are designed to identify these.

7 ASSESSMENT AND MANAGEMENT OF RISK

The intervention is comprised of promising components identified by a systematic literature review, and developed during consultations with professionals, PPI involvement, and carer reference panels with a range of expertise, therefore it is unlikely that the intervention will have significant adverse

effects. Furthermore, this intervention addresses the concerns outlined in the policies described in section 6.2.The intervention will not inhibit the "usual care" that the residents will receive and clinical responsibility for the resident's care will, as per usual practice, remain with their GP, therefore the risk of any harm is minimal.

Study assessments for the residents and the residents' care partners have been kept as brief as possible in order to minimise any potential burden. If the resident becomes upset or uncomfortable in any way with the assessment process, the researcher will stop the assessment immediately and report this to the care home staff and/or the resident's care partner. Withdrawing from the study will not affect their usual standard of care.

If the care partner becomes upset during the research process, the researcher will stop the research activity. The researcher will, with the care partner's permission ask them if they want to have a break from the assessment, continue or to stop. If the care partner wishes to stop then the research activity will be brought to a close. The research staff collecting data will be given training and supervision on all of the study assessment tools and care partner interview schedule.

If staff members become upset or uncomfortable taking part in any of the research activities, a member of the research team will ask if they would like a break or wish to stop. Any problems will be documented. If substantial changes to the protocol are needed we will seek approval of proposed changes from the Research Ethics Committee. Adverse and serious adverse event recording and monitoring will be compliant with the PRIMENT CTU Standard Operating Procedure 12 (Safety Management version 1.2 August 2012). Principles of Good Clinical Practice will be upheld throughout the study.

If we discover issues of malpractice, maltreatment or serious neglect, to the degree that the relevant local authority's safeguarding procedures are triggered, we will in this circumstance be required to break resident confidentiality and inform the relevant authorities, following whichever standard local authority safeguarding procedures are in operation.

This study is categorised as:

Type A = no higher than the risk of standard medical care

8 OBJECTIVES

Primary:

The purpose of this study is to indicate whether a further definitive study is warranted.

Secondary:

The pilot trial seeks to address the following objectives:

1. Establish whether resident consent procedures allow the collection of sufficient individual level data;
2. Assess the effectiveness of the implementation strategy;
3. Assess fidelity to the intervention;
4. Assess the level of nursing home staff engagement with the intervention;
5. Investigate whether the intervention would be sustainable outside the context of a trial;
6. Assess potential primary and secondary outcomes for a definitive trial:
7. To collect cost and outcome data for use in an economic evaluation;
8. Estimate the probability that the intervention is cost-effective;
9. Establish the key cost components through economic analysis and the expected value of perfect information (EVPI);
10. Measure the completeness of data collection, completion of documentation and return rate of questionnaires.

9 MAIN OUTCOMES

The primary objective of this project is to conduct a pilot trial of the BHiRCH study intervention in 14 care homes is to identify whether a further definitive study is warranted. The primary outcome of the pilot study will be a reduction in acute hospital admissions for respiratory infections, urinary tract infections, dehydration and exacerbation of chronic heart failure.

Other than the outcomes described in Section 8.1 the other secondary outcomes are detailed in Tables 1, 2 ,3 and 4. Secondary outcomes which can be collected via standardised evidence-based questionnaires are outlined below:

- The Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001) will be used to calculate service costs and total costs of care. Information is collected on the current living arrangements, use of hospital, community-based services prior to the intervention and the in the following 3 months. The data collected through the CSRI can be used to calculate service costs and total costs of care.

- The Barthel Index (Mahoney & Barthel, 1965) will be used to assess resident's level of function in Activities of daily living and is scored in increments of 5 points (highest possible total score = 100). The values assigned to each item are weighted according to the amount of physical assistance required if the resident cannot perform the activity independently. The 10 ADL items assessed in the Barthel Index are 1) bowel control, 2) bladder control, 3) personal hygiene, 4) toilet transfer, 5) bathtub transfer, 6) feeding, 7) dressing, 8) wheelchair transfer to and from bed, 9) walking (wheelchair management if patient is nonambulatory), and 10) ascending and descending stairs. It has adequate reliability and validity (Fricke &Unsworth, 1997).

- Organisational support for giving person centred care (P-CAT; Edvardsson et al. 2010), measures the extent to which care home staff perceive the care they provide as being person-centred. The P-CAT consists of 13-items formulated as statements about the content of care, the environment, and organization. A total score is calculated, and higher values indicate a higher degree of person-centredness in a possible range of 13–65. Psychometric analysis revealed that the P-CAT was valid and homogeneous by factor, item and content analyses. Cronbach's alpha was satisfactory for the total scale (0.84), and the three subscales had values of 0.81, 0.77, and 0.31 respectively. Test-retest reliability were evaluated (n = 26) and all analyses indicated satisfactory estimates.

- Nurse ratings of communication with primary care questionnaire (Tjia et al., 2009) was developed to assess nurse-physician communication in the long-term care setting. It is an 18-item questionnaire. Questions address aspects of communication previously described in the published literature, including openness, mutual understanding and language comprehension, frustration with the interaction and professional respect, nurse preparedness, time burden and logistical barriers to communication. Questions are rated on a 5-point Likert scale [range 1 (almost never) to 5 (almost always)].

- The perceived knowledge and skills for early detection of changes in health questionnaire was developed after the feasibility study by the BHiRCH team. Each statement refers to the key knowledge and skills which are needed for nurses to effectively carry out the BHiRCH intervention. This questionnaire will provide a measure of knowledge and skills before, during and after the intervention. Questions are rated on a 5-point likert scale [range 1 (disagree completely) to 5 (agree completely)]. This questionnaire is not yet a standardised evidenced-based questionnaire.

- Quality of life (EQ-5D-5L; Herdman et al., 2011) is a generic instrument consisting of a self-administered health index and a visual analogue scale (VAS), a 20-cm scale in which respondents (the residents and the care partner) are asked to rate their current health state. It is a brief instrument, representing five dimensions of health –related quality of life, as opposed to quality of life in general. The EQ-5D contains five domains: mobility, self-care, pain/discomfort, usual activities and anxiety/depression. There are 5 levels per dimension: no problems, slight problems, moderate problems, severe problems, and extreme problems. The respondent is asked to indicate his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state. Respondents are asked to mark their current health state on a 100-point VAS scale, with 100 representing the 'best imaginable health state' and 0 representing the 'worst imaginable health state'. In the proxy version, the care partner or staff member is asked to answer the questions giving their own view of the resident's QoL, as opposed to attempting to provide the person's own view. Index-based values ('utilities') are a major feature of the EQ-5D instrument, facilitating the calculation of quality-adjusted life years (QALYs). The EQ-5D-5L appears to be a valid extension of the 3-level system which improves upon the measurement properties, reducing the ceiling while improving discriminatory power and establishing convergent and known-groups validity (Janssen et al., 2013).

- We will explore the "avoidability" of hospital admissions using techniques trialled in the PDG. We will select a random sample of up to 30 participants who go to hospital and the research team will use the Structured Implicit Record Review (SIRR) tool, developed by Saliba and Ouslander (Ouslander, 2009), to extract relevant data from their care home records and where possible other healthcare notes. We will convene 2 expert multidisciplinary adjudication panels (one in London and one in Bradford) consisting of nurses from care of the elderly and district nursing, doctors (geriatricians and general practitioners) and care home managers, including family carers where possible, to use these anonymised SIRR tool data to assess whether the admission was "avoidable" or not. In the USA this has been shown to have 89% agreement for hospitalization (kappa 0.779) (Ouslander, 2009). This will inform us whether in the care home setting in the UK, hospital admission for an ACS condition is a reliable proxy marker for an "avoidable" admission.

10 PILOT TRIAL MAIN OUTCOMES

The pilot trial seeks to address the following outcomes:

1. Whether a further definitive study is warranted;
2. Establish whether resident consent procedures allow the collection of sufficient individual level data;
3. Assess the effectiveness of the implementation strategy;
4. Assess fidelity to the intervention;
5. Assess the level of nursing home staff engagement with the intervention;
6. Investigate whether the intervention would be sustainable outside the context of a trial;
7. Assess potential primary and secondary outcomes for a definitive trial:
8. To collect cost and outcome data for use in an economic evaluation;
9. Estimate the probability that the intervention is cost-effective;
10. Establish the key cost components through economic analysis and the expected value of perfect information (EVPI);
11. Measure the completeness of data collection, completion of documentation and return rate of questionnaires.

11 SAMPLE SIZE AND RECRUITMENT

11.1.1 SAMPLE SIZE CALCULATION

This is a pilot trial and as such a power calculation is not relevant.

12 STUDY DESIGN

We will conduct a cluster randomised trial in nursing homes. This intervention acts upon a group of people (the nursing home staff who work with residents and their family carers) and thus the nursing home will be the unit of intervention, allocation and analysis.

12.1 CARE HOME RECRUITMENT

Inclusion criteria

Nursing homes will be recruited who express an interest in the project, have adequate staffing for the intervention, and have the capacity to implement the different components, and take part in/support research activities.

Exclusion criteria

Nursing homes who are placed in special measures by the Care Quality Commission.

Recruitment

The identification of homes will be coordinated by local Clinical Research Networks, and through local contacts via the CI's clinical post at North Middlesex University Hospital with Barnet Enfield and Haringey Mental Health Trust. Recruitment activities will be supported by NOCLOR research support services, the North Thames Clinical Research Network and Yorkshire Care Home Research Network. We will approach the managers by phone, following up by a face to face visit, gain their written permission and that of the care home owner or regional manager.

Once care homes have been recruited into the study, each care home manager will nominate a member of staff to become a 'research facilitator'. The research facilitator will support the research team with recruitment activities, and ensuring individual level data collected without consent from the resident is pseudoanonymised prior to being given to the research team. This will be achieved by a member of the care home staff removing the name of the participant and replacing with an ID number before passing this over to the research team. The research facilitator will not be involved in implementing the intervention e.g. being a practice development champion or being a member of the practice development support group. However, if allocated to the intervention, the research facilitator will have an understanding of how project materials are used. We will also aim to put a link to our project website onto the care home website, with the permission of the care home manager. Care homes which are randomised to the intervention will receive a payment of £1500, and care homes which are randomised to the control group will receive £1000. These payments are provided to reimburse the time care home staff have spent being involved in research activities.

13 SELECTION OF PARTICIPANTS

13.1 INCLUSION CRITERIA

The study implements an enhanced version of usual care and because of the clustered nature of the setting this will be implemented across the care home. All English speaking staff and residents over the age of 65 and their care partners will be invited to be involved in the collection of individual level outcome data.

13.2 EXCLUSION CRITERIA

Residents receiving end of life treatment or palliative care, under 65, those who are not English speaking or those who have stated they do not wish to be involved in research.

Care partners will be excluded from the project, and no more data will be collected if their relative/friend passes away during the project.

14 STUDY PROCEDURES AND SCHEDULE OF ASSESSMENTS

14.1 PARTICIPANT IDENTIFICATION

Posters about the pilot trial will be placed within the home to increase awareness, and there will also be a sign-up sheet within the home where potential participants can show their interest by providing their contact details. We will publicise the project where possible using established communication between the care home and family members etc., such as newsletters or other forms of communication. One 'launch' event will be organised in each care home whereby the research team, members of staff in the care home, and members of the Carer Reference Panels will explain the study and distribute recruitment literature. There will be a 'launch event' poster displayed within the home, and the launch event poster will also be posted out to relatives/friends of the residents by the care home.

Residents: The care home staff, or the nominated research facilitator (who is also a member of care home staff) at the care home will provide the researcher with a list of all care home residents (initials only) so that each resident can be assigned an ID number. From this list the member of care home staff will identify which residents are potentially eligible to participate in the individual data collection. All potentially eligible residents will be approached by a member of staff to ask if resident whether a member of the research team can speak with them. If the research team judges that the resident lacks capacity to consent to participate in this research study, a member of staff at the care home will contact a personal consultee (or a professional consultee if a personal consultee is not available) and ask them whether the research team can discuss the project with them.

Members of staff will inform the researcher which residents have a condition which may compromise their capacity to consent to this research, in order to determine whether a capacity assessment from the research team is required. Where necessary, the research team will conduct a decision-specific capacity assessment with respect to the participation in this pilot trial.

We will ask the care home manager or a member of the team in each care home to:

1. Provide researcher with an pseudo-anonymised (3 initials) list of all care home residents;
2. Use a list to identify potentially eligible residents;
3. Ask the eligible residents if the researcher can approach them;
4. Identify those residents who have a condition which may compromise their capacity to consent to this research, in order to determine whether a capacity assessment is required.
5. For those residents who have a condition which may compromise their capacity to consent to this research, we will conduct a mental capacity assessment.
    - In the circumstances where the research team judge that the resident lacks capacity to consent to this research project, we will ask a member of staff at the care home to contact the resident's care partner to seek agreement for the care partner to act as personal consultee. This will be achieved by sending information sheets about the study. In their role as personal consultee they will be asked to determine whether participation in the study was in the person's best interests.

Care partners: Care partners associated with the residents who wish to be involved in the study will be contacted by a member of the care home staff (in particular the nominated research facilitator) to ascertain whether they can be contacted by the research team. A script explaining the study to potential participants will be given to care home staff who are contacting care partners over the phone. Furthermore, if the care partner would like more information or if they are not contactable by phone information sheets and project leaflets explaining the project will be sent out to care partners in the post along with a cover letter and a reply slip with a freepost envelope. If the care partner completes the reply slip with their contact details the research team will give them a call to explain the study further.

Care home staff: All care home staff will be asked if they wish to be involved in collection of questionnaire data. All staff will be asked if they wish to take part in the qualitative interviews for the study, however only 5 care home managers, 5 nurses, 5 care assistants will be interviewed across the 7 intervention homes.

14.2 INFORMED CONSENT PROCEDURE

Our intervention will be implemented at the care home level rather than individual. Individual consent will not be required to receive the intervention. Care home managers will not be providing any individually identifiable participant data, but will be providing consent on behalf of residents (who have not provided individual consent) for the research staff to collect pseudoanonymised data (ID number) concerning care home demographics, care home level hospitalisation data, hospital admissions, use of project materials such as the number of Stop and Watch, and care pathway documents completed.

Where we will be collecting individual level data, i.e. resident quality of life and measures from care home staff and care partners, we will be collecting individual consent or consultee consent. Furthermore, individual level consent will be sought prior to the qualitative interviews being conducted. Research Ethics Committee application will be to one "flagged" to consider research on adults who may lack capacity.

Members of staff will inform the researcher which residents have a condition which may compromise their capacity to consent to this research, in order to determine whether a capacity assessment from the research team is required. Where necessary, the research team will conduct a decision-specific capacity assessment with respect to the participation in this pilot trial. Capacity will be assessed in accordance with the Mental Capacity Act (UK) 2005. A person is unable to make a decision for himself if he is unable to:

a) to understand the information relevant to the decision,
b) to retain that information,
c) to use or weigh that information as part of the process of making the decision, or
d) to communicate his decision (whether by talking, using sign language or any other means)

Residents with dementia may be unable to give fully informed consent. Following methods piloted in our feasibility study and in accordance with the Mental Capacity Act (UK) 2005, if the resident is found to lack capacity to consent to participate in the individual data collection by the member of the research team, we will seek assent from their care partner or someone close to the person to act as a "personal consultee". If no "personal consultee" is available, or if the personal consultee has not been recently involved in the residents care the RA will nominate someone to act in this capacity as a "professional consultee". If a resident loses capacity during the study the original consent form will no longer be valid. In these circumstances an appropriate consultee will be found before continuing with the study. At the beginning of the study, the care home manager will have a discussion with the research team to agree on an appropriate professional consultee. The process of nominating a professional consultee will follow the guidance stated in Section 32 (3) of the Mental Capacity Act 2005. This guidance states that a member of health and social care staff with a professional relationship to the resident could be nominated as a professional consultee if this person has no connection with the project and, in particular, that they are free from potential influence, such as being junior to a member of the research team. In previous projects this has been a community matron or a local senior district nurse. During the course of the study we will consider process or ongoing consent, checking with the resident or consultee that the participant is still willing to participate in the project.

Trained members of the research team will take consent or gain agreement for a resident's participation in the study (where they have capacity to consent to research) following adequate explanation of the aims, methods, anticipated benefits and potential hazards of the study. We will stress that the participants are under no obligation to enter the study and that they can withdraw at any time during the study, without having to give a reason. A copy of the signed Informed consent form will be given to the participant. The original signed form will be retained at the study site and a copy placed in the medical notes. No pilot data will be collected on an individual prior to taking consent from the participant.

Care home staff, residents and care partners will give fully informed consent for their own participation in outcomes measurement, qualitative interviews. During the consent process potential participants will be informed that they can opt out of further data collection either by speaking with a member of the research team directly or by contacting the team by phone or post using the contact details outlined on the information sheet provided. During each assessment a member of the research team will confirm that the participant wishes to continue with data collection (process consent).

14.3 PARTICIPANT SAFETY

If information disclosed or discovered leads the research team to believe that a participant is at

significant risk, the researcher will discuss this with their supervisor. If appropriate they will approach the participant and seek their consent for disclosure. The information sheet will specify that "we respect confidentiality but cannot keep it a secret if anyone is being seriously harmed or is at high risk of serious harm". If there is reason to believe that harm is occurring or there is a high risk it is likely to occur, we will report this to the care home without consent if this is refused. We will adhere to local authority safeguarding procedures.

14.4 RANDOMISATION PROCEDURES

Care homes will be randomised to intervention (4 in Yorkshire and 3 in Greater London, 7 in total) or "usual care" (4 in Yorkshire and 3 in Greater London, 7 in total) between Greater London and Yorkshire, the randomisation being stratified by location. Randomisation will be undertaken by an independent statistician from the CTU. All homes will be randomised at the same time, just prior to the intervention starting.

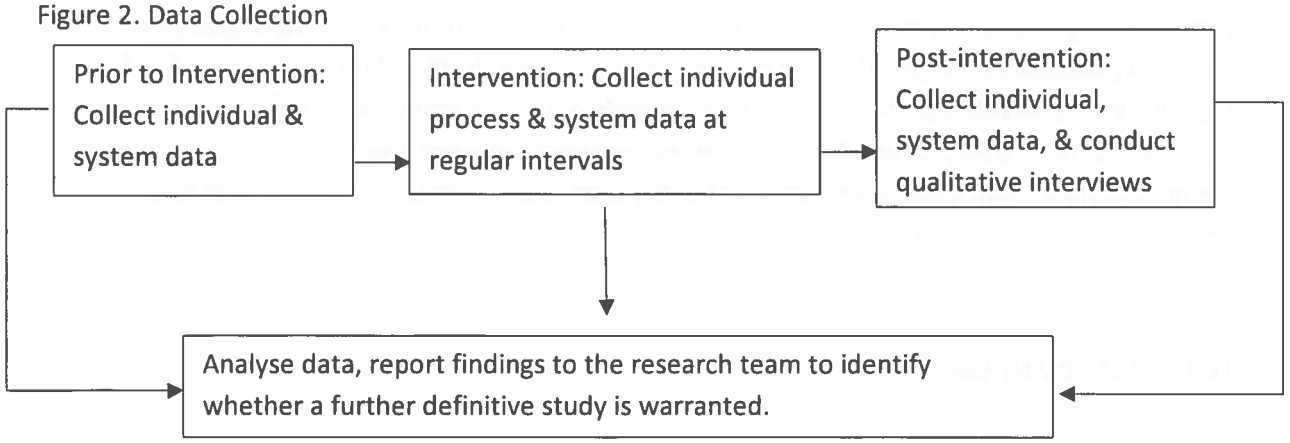
14.5 UNBLINDING

Blinding in this study may not be feasible for the research staff collecting the data, as the outcome measures will be different depending on intervention allocation. Data will be analysed by the statisticians and health economists blind to allocation. The randomisation variable will be supplied to them unlabelled, and main analysis completed using this. The blinding will be broken and any analyses which necessitate knowing the randomised allocation (for example, analyses carried out on one randomised arm only) will then be carried out.

14.6 BASELINE ASSESSMENTS

At study baseline, defined in this study as the "pre-intervention" months we will collect data outlined in Tables 1, 2, 3 and Appendix A. The questionnaires for residents, care staff and family carers/friends/care partners will take approximately 20 minutes. A flow chart depicting data collected at each time point can be found in Figure 2 below.-

Figure 2. Data Collection



14.7 SITE SET-UP

The research staff will meet with the research facilitator and care home staff to discuss issues directly relating to the setting up and the integration of the intervention and research activities within their local systems (Step 4 in Figure 1). This will also highlight the importance of each component of the intervention, and identify what contributions are required from care home staff. A checklist has been created which details these requirements and expectations.

14.8 WORKSHOP

Members of the research team will lead a one-day workshop for Practice Development Champions. This will cover:

- Introduction to the four conditions (respiratory infections, urinary tract infections, dehydration & acute exacerbation of chronic heart failure).
- Key elements of how to bring about change within an organization.
- How to establish and coordinate the Practice Development Support Group of care home staff, care partners, and external staff (e.g. primary care professionals) who can support the introduction and embedding of the change.
- Strategies for engaging people and encouraging continued participation.
- Strategies for gathering routinely collected data to monitor implementation of the programme.
- An overview of the *Stop and Watch* Early Warning Tool, the *Care Pathway* and effective communication with primary care staff.
- Potential changes to communication flows and recording of information about residents.

14.9 INTERVENTION PROCEDURES

A project handbook has been created for staff use (Appendix B), and a Practice Development Workbook for Nursing, Health and Social Care Teams: Resources for Health and Social Care Teams (Dewing et al., 2014) will be provided.

The intervention will commence after recruitment and randomisation.

The BHiRCH programme is a complex intervention, with 4 key components. These are:

1. Early Warning Tool (*Stop and Watch* Early Warning Tool) (Appendix C).
2. *Care Pathway* (clinical guidance and decision support system) (Appendix D).
3. Structured method for communicating with primary care (SBAR) (Appendix E).
4. Implementation support from practice development champions.

1. Early Warning Tool (*Stop and Watch* Early Warning Tool): This tool is widely used in the US. It highlights simple signs and behaviours to identify common, but nonspecific changes in a resident's condition that seem out of the ordinary for the resident. The tool is intended to be used as an alert to determine if further assessment of a resident by a registered nurse (with the *Care Pathway*) is necessary. Care assistants or nurses will use the *Stop and Watch* Early Warning Tool when: 1) they notice a change; or 2) anyone else in the care home (including residents, other staff and care partners) notices a change; at the latest by the end of the shift. Care assistants or nurses complete the paper-based *Stop and Watch* Early Warning Tool, circling the changes they observed, and notify the nurse of this change, giving them the completed *Stop and Watch* Early Warning Tool. Practice Development Champions in collaboration with their Practice Development Support Group will decide how best to provide care assistants and nurses with ready access to the *Stop and Watch* Early Warning Tool; and where completed forms will be stored.

2. **Care pathway**: The *Care Pathway* is a clinical guidance and decision support system that includes Primary and Secondary assessment of respiratory infection, urinary tract infection, dehydration, and acute exacerbation of chronic heart failure. Primary assessment is the first level or initial assessment which comprises screening type questions and secondary assessment is the more detailed level of assessment of the person. The *Care Pathway* has been designed to facilitate early assessment and diagnosis of acute changes in health; and to prompt early intervention. Nurses use the *Care Pathway*, having been alerted to a change in a resident's health by care assistants as soon as possible. If the Primary or Secondary Assessment result in an ambiguous outcome, the *Care Pathway* should be administered repeatedly at 6-hour intervals, until such time as the nurse is satisfied from the evidence collected, that the issues of concern have resolved and/or appropriate intervention has been instigated. The nurse will conduct the Primary and Secondary assessment following the steps of the *Care Pathway,* consequently the nurse will record the outcome of the Primary and Secondary assessment and their implications for care practice (i.e. care plan) in the residents' care records The nurse will then make a clinical decision about the next course of action which will include one or more of the following actions:
   a. If the assessment is inconclusive, but the nurse judges that the resident's condition is not an immediate concern they can:
      i. Direct further general monitoring using the *Stop and Watch* Early Warning Tool (as often as deemed necessary), or
      ii. Direct monitoring for specific symptoms of the resident's condition.
   b. If the nurse determines that the resident's condition can be treated in the care home, they can initiate treatment.
   c. If the assessment indicates a potential diagnosis, or there is immediate concern about a resident's condition, they can communicate with primary care using the SBAR process (Appendix E). This process facilitates structured efficient communication to ensure the relevant information is passed onto primary care by outlining the following four

categories (situation, background, assessment, recommendation) .
The nurse will feed back information about the course of action to the relevant staff on each shift, and to the domestic staff and family members, close friends or care partners, as appropriate. Copies of the completed *Care Pathway* will be kept with the resident's record.

3. Structured method for communicating with primary care: The SBAR (Situation, Background, Assessment, Recommendation) is a structured method for communicating critical information about residents to primary care. This will contribute to appropriate action and increased resident safety. Nurses use the SBAR to communicate critical information about residents to primary care and out-of-hours staff. The nurse will use the SBAR when they want primary care input into the care of one of their residents who they have assessed using the *Care Pathway* as being at risk of decline. Before making a call to primary care, the nurse should organise the briefing information on paper using the four elements (Situation, Background, Assessment and Recommendation) in sequence. Only the most relevant data are included. Presenting the briefing in this format will help primary care staff to quickly understand the situation. The SBAR tool can be attached to the *Care Pathway*.
It is important to be clear about the specific role or roles that each family member, close friend or care partner would like to have.

4. Implementation support: Creating sustainable change in care homes is challenging. This intervention includes a focus on support for implementing the changes. We have drawn on change management methodology including the use of champions and the Promoting Action on Research Implementation in Health Services (PARiHS) framework (which emphasises the relationship between context, evidence and facilitation). The care home manager and external facilitators will identify two nurses to serve as Practice Development Champions in the care home prior to the intervention. They are selected based on the person specification (see below). Practice Development Champions in turn select members of a Practice Development Support Group to support their work in the care home. Members of the Practice Development Support Group are selected following the one-day workshop attended by Practice Development Champions. Criteria for identification of Practice Development Support Group members will be covered in the one-day workshop for Practice Development Champions.

Practice Development Champion person specification

The Practice Development Champion will:

- Be a Registered Nurse.
- Have been working in the nursing home for at least 6 months.

When selecting a Practice Development Champion we are looking for someone who:

- Has some knowledge of good practice in supporting health care and has an interest in the topic *(can demonstrate some essential knowledge of the management of the 4 conditions: chronic heart failure, respiratory infections, UTI, dehydration).*
- Knows co-workers *(has been in the organisation long enough to know the staff and how they work).*
- Knows the environment *(has some insight into the culture of the setting).*
- Knows the organisation *(knows their way around the organisation, e.g. who's who, policies in place, decision-making structures).*
- Possesses effective communication skills *(could include attributes of being open minded, being creative, has experience of managing meetings/groups, able to talk in front of groups).*
- Is self-aware and resilient *(has insight into their support needs, but is also not afraid of challenge/conflict; willing to engage in own professional development).*
- Is reliable and dependable *(has time they can dedicate to this work [in writing from their manager]; carries through with responsibilities, meets deadlines or negotiates otherwise; is not intending to be on extended leave during intervention period).*
- Is respected by co-workers (*has a good relationship with co-workers which means they will be listened to with respect to new ideas*).

These criteria are ESSENTIAL and are NOT listed in a hierarchy/order of importance, i.e. they are all equally important.

From Seers et al 2012 FIRE (facilitating implementation of research evidence): a study protocol

http://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-25

Practice Development Champions will be supported in their role by:

- Staff handbook (implementation focused)
- Practice development workbook
- Monthly telephone conferences with a member of the research team (not involved in data collection).
- Weekly reminders to complete Practice Development Champion log
- Providing a summary of the current knowledge and skill level of the members of staff who completed the perceived knowledge and skills questionnaire. This information will be used to signpost members of staff to relevant resources. The summary of results and recommended resources presented to the Practice Development Champions will be provided during the monthly support conference and will be anonymous at the level of the care home.

14.10 SUBSEQUENT ASSESSMENTS

Please refer to Appendix A.

14.11 METHODS

14.12 DEFINITION OF END OF STUDY

The end of the study will be when post-intervention data collection is complete.

14.13 DISCONTINUATION/WITHDRAWAL OF PARTICIPANTS

The majority of withdrawals will be due to death, leaving the care home and no longer wishing to take part in the intervention or data collection. All withdrawals of enrolled subjects from the study will be reported and explained on the CRFs. Withdrawal forms will note the reason for withdrawal, the timing during the study at which the participant wished to withdraw and whether they wish their data to be destroyed. The following statement will be included in all study consent forms 'I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected'. It is unlikely that this low risk study will be prematurely stopped.

14.14 CONCOMITANT MEDICATION

Usual care including medications and treatments will be permitted throughout the duration of the pilot trial.

14.15 POST-STUDY ARRANGEMENTS

The intervention support will not be provided after the study has ended as this is a pilot trial. If participating care homes wish to continue with the intervention after the pilot trial they will be free to do so. Control homes will be offered physical healthcare skills training at the end of the Pilot Trial.

15 DATA MANAGEMENT AND QUALITY ASSURANCE

All data will be collected and handled in accordance with the UK Data Protection Act 1998, PRIMENT SOPs and GCP.

15.1 CONFIDENTIALITY

The Case Report Forms (CRFs) will not bear the participant's name. The participant's initials, date of birth and trial identification number, will be used for identification and all data will be handled according to PRIMENT's SOP Managing Personal data.

15.2 DATA COLLECTION TOOLS

The data collection tools will be created according to PRIMENT's SOP Development, Review and Approval of Case Report Forms.

15.3 TRIAL DATABASE

The CRFs will be entered into a web-based clinical data management system, Red Pill, provided by Sealed Envelope through PRIMENT. Sealed Envelope has been assessed by PRIMENT to ensure that adequate processes are in place and are being followed for quality management, software development and security. The trial database services and support will be delivered through a contract signed by Sealed Envelope and UCL. PRIMENT's SOPs Validating Sealed Envelope Systems

and Change Control for Sealed Envelope Systems will be followed to set up and manage changes to the trial database. At the end of the trial prior to analysis PRIMENT's SOP Database Lock, Unlock and Closure will be followed.

15.4 DATA COLLECTION AND HANDLING

All data will be collected and handled in accordance with PRIMENT's SOP Data Handling.

It will be the responsibility of the investigator to ensure the accuracy of all data entered in the CRFs. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

Original consent forms, screening logs, original questionnaires and transcripts will be transferred securely from Bradford University to UCL via registered mail to ensure that the data is delivered only to the person to whom it is addressed, or another member of the research team who is acting on their behalf.

Original consent forms and questionnaires will be stored in lockable filing cabinets, or a locked room which only the research team can access at University College London. Photocopies of the consent forms and questionnaires will be stored in lockable filing cabinets, or a locked room which only the research team can access at the University of Bradford. The audio recordings from qualitative interviews and transcripts will be password protected and saved on a secured shared drive which only members of the research team can access. All sensitive personal data will be transferred to UCL securely via Data Safe Haven. The SLMS Data Safe Haven technical infrastructure has been built specifically to host sensitive data. The hosting is on a thin client system with dual factor authentication. This is a multi-user system with permission-based access control. There is a standard process for granting and revoking access and system privileges are limited to a small number of technical staff who have received training in information security.

15.5 DATA OWNERSHIP

At the end of the study, the data belongs to Bradford and UCL between whom a data sharing agreement will be signed.

16 RECORD KEEPING AND ARCHIVING

Archiving will be authorised by UCL following submission of the end of study report. The Chief Investigator (ELS) is responsible for the secure archiving of essential study documents and the study database as per their University. Data will be securely transferred from Bradford to UCL. All essential documents will be archived at UCL in accordance with UCL guidelines for a minimum of 20 years after completion of study. UCL sponsored studies adhere to a 20 year archiving period to allow for access to documents, audits and inspections over a sufficient time period. Destruction of essential documents will be authorised by UCL.

17 STATISTICAL CONSIDERATIONS

Louise Marston is the study statistician who will be responsible for all statistical aspects of the study from design through to analysis and dissemination. The SAS statistical programme will be utilised for the randomisation process.

17.1 STATISTICAL ANALYSES

Quantitative data will be entered into electronic CRFs by the RFs at each site and thus directly entered into a database via an encrypted website supplied through PRIMENT. The database application will be GCP-compliant and access will be restricted to authorised individuals. PRIMENT will conduct the analyses. We shall follow CONSORT guidelines for the reporting of randomised trials however, given that this is a pilot study, our analysis will be mainly descriptive and will focus on the recruitment, participant characteristics, other baseline and outcome variables, loss to follow-up and any serious adverse events. We shall provide a descriptive analysis of all the data and compare rates of hospital admission for ACS conditions and other important outcomes between the control and intervention groups through the calculation of confidence intervals. These, along with estimates of the standard deviations of the other outcome measures and of intra-class correlation coefficients (ICCs) will assist in calculating power and sample size for a full trial. We will summarise the completeness of data collection on all outcome measures and, for questionnaires, we will describe the distributions and the response rates.

18 QUALITATIVE METHODS

Our qualitative work supports the analysis of the implementation process and will provide important information on the effectiveness of the implementation strategy. All participants will give their informed consent, including for recording of their interviews.

The research team will conduct 20 semi-structured interviews with 5 care home managers, 5 nurses, 5 care assistants and 5 care partners from the 7 intervention homes across both sites. Interviews will explore participants' views on the effectiveness of the intervention in preventing avoidable hospital admissions. Interviews will also explore the experiences of implementing the intervention including the views of those receiving the intervention, and will last between 30 to 45 minutes. We will include a range of care home sizes and length of time working in the home. Family carers will be purposively sampled to ensure a range of gender, age and types of family carer. We will ensure that family carers who may not visit the care home regularly can participate by offering the option of telephone interviews. A verbatim transcript of the discussion will be made and the data will be entered into qualitative analysis software (NVIVO) and key themes coded using framework analysis (Ritchie & Lewis, 2003). Furthermore, a sample of the interviews will be analysed by the programme manager and the lead for qualitative analysis to check levels of coding agreement with the template.

19 ECONOMIC EVALUATION

Economic evaluation is recommended in developing and piloting interventions to identify weaknesses and suggest refinements. Such data assist the design of subsequent effectiveness studies, estimating potential benefits relative to costs, and research design. It informs planning of future economic analyses, sources of data required and how best to collect these data. The analyses will conform to accepted economic evaluation methods (NICE, 2008).

We will assess the feasibility of calculating the quality adjusted life years (QALYs) for residents in the intervention and control homes for the duration of the study, using the EQ-5D. In the societal level analysis a calculation of carers' QALYs will also be included.

This intervention has the potential to impact on expenditure across a number of stakeholders. The cost of a nursing home bed day for an older person has been estimated at between £522 and £1080 per patient per week, with care in London being almost twice as costly in some instances. The actual cost of care may be incurred by the Local Authority, the NHS, Department for Work and Pensions and/or the individual depending on the type of care home and which cost components are included. Yet the amount of primary care resource use by residents in nursing homes is currently unknown (Curtis et al., 2012). Avoidable admissions to hospital present an opportunity cost to the NHS, in that those resources used by residents could have been used elsewhere. The direct cost to a nursing home of a resident being in hospital is unclear, given that the bed may remain empty but staffing unaffected. Hence we will investigate the complex interplay of costs associated with this intervention.

We will calculate the costs associated with the intervention, including the cost of enhancing staff's knowledge and skills and the resources associated with the implementation of the intervention. The resource use associated with hospital admissions, primary care and other NHS and social care costs will be collected from residents' files for the intervention and control homes. We will assess the feasibility of asking residents directly via questionnaires where collection of the information from resident files is not possible. Resource use will be costed using published sources, PSSRU and reference costs (Curtis et al., 2012). Costs will be reported from an NHS/PSS, government and societal perspective in order to capture the different areas of expenditure. We will work with nursing home staff, family carers and commissioners to assess how best to report costs, including any areas of cost savings, to interested stakeholders.

We will provide an initial estimate of the incremental mean cost per QALY gained in the intervention compared to control homes for the duration of the trial. The mean QALY per resident will be calculated as the area under the curve for the duration of the trial, adjusting for baseline values. Confidence intervals will be constructed using non-parametric bootstrapping with replacement. Cost-effectiveness acceptability curves, showing the percentage of cases that the intervention is cost-effective for a range of values of willingness to pay for a QALY gained, will be constructed for each of the different costing perspectives and for the different methods of calculating QALYs.

We will model the lifetime costs and outcomes of the intervention compared to controls. This will involve assessing the quality of the published information available, the development of an initial model and identification of which cost and outcome components would benefit most from further research i.e. an extra value of perfect information (EVPI) and an extra value of partial perfect information (EVPPI) analysis.

20 NAME OF COMMITTEES INVOLVED IN STUDY

Two Carer reference Panels (CRP) have been created to ensure public involvement during all stages of the project. They are chaired by Dr Barbara Woodward-Carlton (Bradford) and Shirley Nurock (London), both co-applicants. Each is comprised of 8 family carers of people with dementia and a person living with dementia. The carers are all members of the Alzheimer's Society research volunteer network. Almost all have had a relative with dementia living in a care home. Agenda items have included: recruitment and consent; accessibility of information leaflets; study design and data collection; aims, research questions and PG WPs. For example, the CRP advised on the information sheets requesting that 'Answering the questions can sometimes be tiring but you do not have to answer any questions you do not want to, and you will be free to take a break at any time' be removed as they believed that it was not necessary to say that a 20 minute interview may be tiring. The CRP have also advised on recruitment methods.

International Advisory Group- (IAG) will oversee the research, provide advice and guidance on all aspects, provide strategic PPI oversight, ensure the project remains grounded in real experience and is informed by international best practice and research.

Trial Management Group- includes those individuals responsible for the day-to-day management of the study. The role of the group is to monitor all aspects of the conduct and progress of the study, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the study itself.

Trial Steering Committee- the NIHR Programme Steering Committee includes senior members of the research team and interested external experts, recruited with the approval of the NIHR. Its purpose is to supervise the overall programme, on behalf of NIHR and the Sponsor; provide independent expert advice during the conduct of the programme; and to monitor progress, adherence to the agreed programme, measures of patient safety, and any new evidence from the programme or externally.

21 RECORDING AND REPORTING OF SERIOUS ADVERSE EVENTS AND REACTIONS

21.1 PROCEDURES FOR REPORTING SERIOUS ADVERSE EVENTS

A Serious Adverse Event (SAE) is any untoward occurrence that:

- results in death
- is life-threatening at the time of the event
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital anomaly or birth defect
- Or any other important medical condition

Please see Figure 3 for an example of the safety reporting assessment

An SAE occurring to a research participant should be reported to the main REC where in the opinion of the Chief Investigator (CI) the event was:

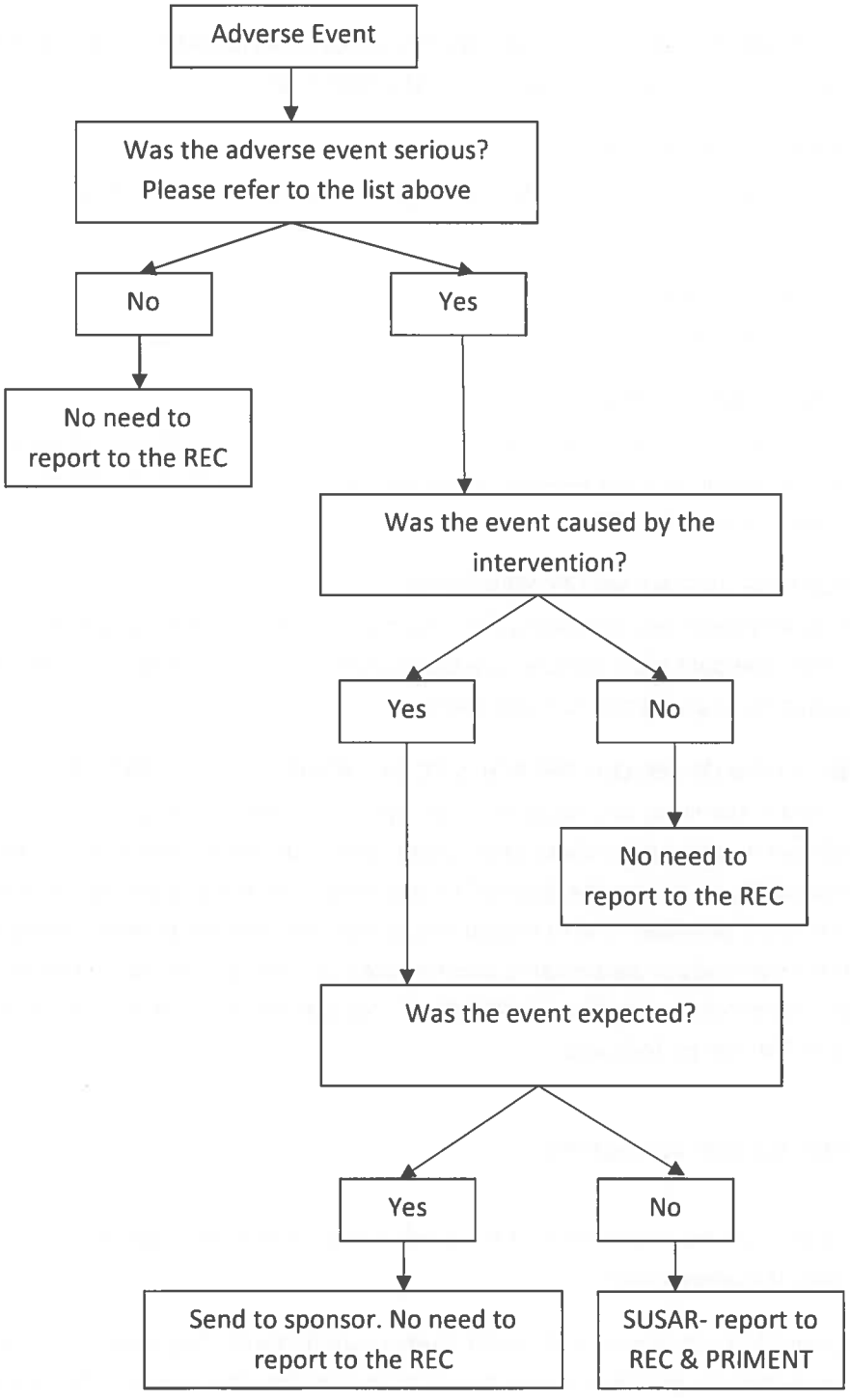
- Related - that is, it resulted from administration of any of the research procedures, and;
- Unexpected - that is, the type of event is not listed in the protocol as an expected occurrence.

In line with HRA guidance, reports of related and unexpected serious adverse events will be reported to the REC that approved the trial. The 'Non-CTIMP Safety Report to REC ' form will be completed and submitted within 15 days of the Chief Investigator becoming aware of the event.

A copy of the completed form should also be sent to PRIMENT on PRIMENTsafetyreport@ucl.ac.uk within the same timeline.

Send all SAEs to the sponsor Rand.D@uclh.nhs.uk, irrespective of the expectedness and relatedness.

Figure 3. Safety Reporting Assessment Flowchart



21.2 PROCEDURES FOR RECORDING AND REPORTING SERIOUS ADVERSE EVENTS

Serious adverse events will be recorded for 30 days after the intervention has finished. No follow-up care will be given as the intervention does not involve the use of drugs.

21.3 THE TYPE AND DURATION OF THE FOLLOW-UP OF PARTICIPANTS AFTER ADVERSE EVENTS

Participants will be followed up until the end of the Pilot Trial.

21.4 NOTIFICATION OF DEATHS

All deaths will be reported to the sponsor Rand.D@uclh.nhs.uk within 72 hours of being made aware.

21.5 REPORTING SUSARS

The Sponsor will notify the REC of all SUSARs within 15 days after the sponsor has learned of them.

21.6 ANNUAL PROGRESS REPORTS

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Chief Investigator will prepare the APR.

21.7 REPORTING URGENT SAFETY MEASURES

If any urgent safety measures are taken, the PI/Sponsor shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to REC of the measures taken and the circumstances giving rise to those measures.

21.8 NOTIFICATION OF SERIOUS BREACHES TO GCP AND/OR THE PROTOCOL

All staff involved in the study are responsible to report breaches to the CI. The CI in collaboration with the TMG will make an immediate assessment, and to decide to who it should be referred. It is the CI's responsibility to inform the Sponsor of any serious breach as soon as they become aware of it (within 24 hours if possible). The CI should also assess whether the potential breach has serious implications for the study or participants at other sites, and initiate any necessary actions immediately. The procedure outlined in PRIMENT's Serious Breaches of Good Clinical Practice or the Study Protocol SOP will be followed.

22 MONITORING AND INSPECTION

A monitoring plan will be established for the study based on the risk assessment. The study will be monitored with the agreed plan.

The investigator(s)/ institution(s) will permit study-related monitoring, audits, REC review, and regulatory inspection(s), providing direct access to source data/documents. Study participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical notes.

23 ETHICS AND REGULATORY REQUIREMENTS

PRIMENT will ensure that the study protocol, information sheets, consent forms, GP letter and submitted supporting documents have been approved by the appropriate regulatory bodies, prior to any participant recruitment. The protocol and all agreed substantial protocol amendments, will be documented and submitted for ethical and regulatory approval prior to implementation.

Prior to participant enrolment into the study, the Chief Investigator/ Principal Investigator or designee will gain regulatory approval from the appropriate bodies. It is the responsibility of the Chief Investigator/ Principal Investigator or designee to ensure that all subsequent amendments gain the necessary approval. The individual's clinician remains responsible for taking immediate action if thought necessary to protect the health and interest of individual participants.
Within 90 days after the end of the study, the CI/Sponsor will ensure that the main REC is notified that the study has finished. If the study is terminated prematurely, those reports will be made within 15 days after the end of the study.

The CI will supply the Sponsor with a summary report of the clinical study, which will then be submitted to the main REC within 1 year after the end of the study.

24 PUBLIC AND PATIENT INVOLVEMENT

The original research proposal was developed in collaboration with DeNDRoN Patient and Public Involvement representatives, Nurock and Woodward-Carlton, who were co-applicants on the Programme Development Grant (PDG) and are co-applicants on this grant.

PPI is present at both strategic and operational levels of the Programme including care partners and care home residents. Strategic PPI oversight is provided through PPI representation on the International Advisory Group.

Ongoing collaboration with PPI members has occurred with both family carers and residents. Each Panel meets six monthly during the Programme. The work of the panels is to engage with and advise on the following: ethics and governance paperwork with respect to information sheets; preparation of the research information and study publicity for residents and family carers; recruitment, consent and data collection processes in care homes; analysis and interpretation of findings; publicity for the study; how to present study to care home family meetings. Resident collaboration in the programme occurred 3 times in the first year of the research programme, in an informal consultations with a group of 7 residents living in one care home. The aim of the PPI involvement by residents was to inform the development study information materials for residents in the feasibility study and the current pilot Trial. PPI has been co-led by KF, SN and BW-C. Role descriptions and responsibilities have been written for PPI roles.

25 FINANCE

The programme grant 'Reducing rates of avoidable hospital admissions: Optimising an evidence-based intervention to improve care for Ambulatory Care Sensitive conditions in nursing homes' (RP-

PG-0612-20010) was awarded by the National Institute of Health Research from 01/03/2015 until 31/05/2018.

26 INSURANCE

University College London holds insurance against claims from participants for injury caused by their participation in the clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent.

Participants may also be able to claim compensation for injury caused by participation in this clinical study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

27 PUBLICATION POLICY

All proposed publications will be agreed by the CI, and will follow the NIHR publications policy and dissemination plan.

28 STATEMENT OF COMPLIANCE

The study will be conducted in compliance with the approved protocol, the UK Regulations, EU GCP and the applicable regulatory requirement(s).

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30 APPENDIX A MAIN OUTCOMES

Study "outcome" data with time points																
Item to be measured	*Domain*	*Purpose*	*Pre-intervention (3-months)*	*Month 1*	*Month 2*	*Month 3*	*Month 4*	*Month 5*	*Month 6*	*Month 7*	*Month 8*	*Month 9*	*Month 10*	*Month 11*	*Month 12*	*Post-intervention*
Care home characteristics	Care home level data Quantitative Control & Intervention homes	Characterise care home	x													
Number participants , eligible, approached,	Recruitment data Care home	Calculate recruitment rate	x													

and number who gave consent	level data Quantitative Control & Intervention homes	Control & Interventi on homes														
Resource use and cost	Care home level data Intervention homes	Calculate the cost of the interventi on Interventi on only														x
Resident, care partner and staff demographics	Individual data Quantitative Control & Intervention homes	Character ise participan ts Control & Interventi on homes	x													
Degree of perceived	Individual	Context	X						x							X

organizational support for providing person-centred care (P-Cat; Edvardsson et al., 2010)	data Quantitative Control & Intervention homes	Control & Intervention homes														
Nurse ratings of communication with primary care (Tjia et al.,2009)	Individual data Quantitative Control & Intervention homes	Identifying change in communication	X						x							X
Perceived knowledge and skills for early detection in changes in health	Individual data Quantitative Control & Intervention homes	Identifying change in perceived knowledge and skills	x						x							X
Identify preferred role	Individual	Identifying	x													

of care partner.	data Quantitative Control & Intervention homes	preferred role														
Carer quality of life using the EQ-5D-5L (Herdman et al., 2011)	Individual data Quantitative Control & Intervention homes	Economics	x						x							x
Resident quality of life using the EQ-5D-5l (Herdman et al., 2011)	Individual data Quantitative Control & Intervention homes	Economics	x						x							x
Resident quality of life using the EQ-5D-5L	Individual data	Economics	x						x							x

(Herdman et al., 2011)Proxy	Quantitative Control & Intervention homes															
Functional ability of residents assessed by Barthel Index (Mahoney & Barthel, 1965)	Individual data Quantitative Control & Intervention homes	Functional ability	x						x							x
Medical consumables such as prescription medication.	Individual data Control & Intervention homes	Economics	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Use of other health and social care services (CSRI)	Individual data Quantitative Control & Intervention	Economics	x	x	x	x	x	x	x	x	x	x	x	x	x	x

	homes															
The number of completed Stop & Watch Early Warning Tool forms during the intervention, including information regarding dates and times. Include breakdown for how many completed during each shift.	Process data Quantitative Intervention only Individual & care home level	Implementation and adherence		x	x	x	x	x	x	x	x	x	x	x	x	
Summary of which changes were circled on the Stop & Watch Early Warning Tool	Process data Quantitative Intervention only	Implementation and outcome		x	x	x	x	x	x	x	x	x	x	x	x	

forms.	Individual & care home level															
Who (care assistant, resident, other staff member, family member, friend) referred/noticed the change on the Stop & Watch Early Warning Tool forms.	Process data Quantitative Intervention only Individual & care home level	Implementation and outcome		x	x	x	x	x	x	x	x	x	x	x	x	
The number of forms where no changes were found using the Stop & Watch Early Warning Tool form.	Process data Quantitative Intervention only Individual & care home level	Implementation and outcome		x	x	x	x	x	x	x	x	x	x	x	x	

Number of Stop & Watch Early Warning Tool forms which resulted in a care pathway being actioned and completed by the nurse.	Process data Quantitative Intervention only Individual & care home level	Implementation and outcome		x	x	x	x	x	x	x	x	x	x	x	x	
The number of care pathways which were completed by the nurse who was initially informed when a change was noticed ('reported to-nurses name) in comparison to another nurse completing the care pathway.	Process data Quantitative Intervention only Individual & care home level	Implementation and outcome		x	x	x	x	x	x	x	x	x	x	x	x	

The number of primary assessments which were conducted using the care pathway.	Process data Quantitative Intervention only Individual & care home level	Implementation, adherence and outcome		x	x	x	x	x	x	x	x	x	x	x	x		
The number of secondary assessments which were conducted using the care pathway.	Process data Quantitative Intervention only Individual & care home level	Implementation, adherence and outcome		x	x	x	x	x	x	x	x	x	x	x	x		
The number of primary and secondary assessments using the care pathway which	Process data Quantitative Intervention only Individual &	Implementation and outcome		x	x	x	x	x	x	x	x	x	x	x	x		

resulted in an ambiguous outcome.	care home level															
The number of care pathways administered 6-hours later if primary and/or secondary assessments using the care pathway resulted in an ambiguous outcome	Process data Quantitative Intervention only Individual & care home level	Implementation, adherence and outcome		x	x	x	x	x	x	x	x	x	x	x	x	
Outcomes of care pathway assessment: - Further general monitoring using the stop and watch tool - Monitoring	Process data Quantitative Intervention only Individual & care home level	Implementation, adherence and outcome		x	x	x	x	x	x	x	x	x	x	x	x	

for specific symptoms - Treatment initiated in care home Condition communicated with primary care (how many times & with who)																
Changes or amendments to the structure or content of the care pathway documents will be noted.	Process data Quantitative Care home level Intervention only	Implementation, adherence and outcome		x	x	x	x	x	x	x	x	x	x	x	x	
Experience of implementing and receiving the intervention and its	Process data Qualitative Interviews Individual	Implementation														x

effectiveness.	Intervention only															
Modifications made to the intervention and implementation support.	Process data Care home level Intervention only	Implementation		x	x	x	x	x	x	x	x	x	x	x	x	
Log of the time spent by the PDCs and PDC support members implementing the intervention	Process data Quantitative Care home level Intervention only	Implementation		x	x	x	x	x	x	x	x	x	x	x	x	
RT will keep detailed field notes of monthly	Process data Qualitative	Implementation		x	x	x	x	x	x	x	x	x	x	x	x	

support calls with Practice Development Champions	Care home level Intervention only															
Completeness of data collection on outcome measures	Process data Quantitative	Outcome														x
Number of acute hospital admissions from respiratory infections, urinary tract infections, dehydration and acute exacerbation of chronic heart failure	System data Quantitative Control & Intervention homes Individual data and care home level	Outcome	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Structured Implicit Record Review (SIRR; Saliba et al., 2000) tool, care home records and healthcare notes to assess whether admissions were avoidable.	System data Quantitative Qualitative Individual Control & Intervention homes	Conduct review as & when hospitalisations occur Outcome														
<u>Care pathway</u> *Primary assessment* How many were indicative for lower respiratory infection, urinary tract infections, dehydration, congestive	System data Quantitative Individual & care home level Intervention only	Outcome		x	x	x	x	x	x	x	x	x	x	x	x	

heart failure? *Secondary assessment* How many were indicative for lower respiratory infection, urinary tract infections, dehydration, congestive heart failure?															
Number of hospital admissions and readmissions	System data Quantitative Individual & care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x

Number of ambulances called	System data Quantitative Individual & care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x
Unscheduled (out of hours) GP visits or telephone contact	System data Quantitative Individual & care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x

Accident and Emergency attendance	System data Quantitative Individual & care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x
Staff turnover	System data Quantitative Care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x
Number of available beds to new residents in the	System data Quantitative	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x

last month																
Length of residents' hospital admissions	System data Quantitative Individual & care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x
Deaths in the last calendar month	System data Quantitative Individual & care home level Control & Intervention homes	Outcome	X	x	x	x	x	x	x	x	x	x	x	x	x	x

31 APPENDIX B PROJECT HANDBOOK

The above project can be found as separate document.

32 APPENDIX C STOP AND WATCH EARLY WARNING TOOL

BHiRCH
Better Health in Residents in Care Homes

Name:

I.D. No:

Stop and Watch
Early Warning Tool

INTERACT
Version 4.0 Tool

If you have identified a change while caring for or observing a resident, please **circle** the change and notify a nurse. Either give the nurse a copy of this tool or review it with her/him as soon as you can.

S Seems different than usual
T Talks or communicates less
O Overall needs more help
P Pain – new or worsening; Participated less in activities

a Ate less
n No bowel movement in 3 days; or diarrhoea
d Drank less

W Weight change
A Agitated or nervous more than usual
T Tired, weak, confused, or drowsy
C Change in skin colour or condition
H Help with walking, transferring, toileting more than usual

☐ Check here if no change noted while monitoring high risk patient

Initial change noticed by — *Date and Time (am/pm)*
Family ☐ *Care Assistant* ☐ *Nurse* ☐ *Other* ☐

Stop and Watch completed by — *Date and Time (am/pm)*
Care Assistant ☐ *Nurse* ☐

Course of action — *Date and Time (am/pm)*

Time to complete — *Date and Time (am/pm)*

33 APPENDIX D CARE PATHWAY

BHiRCH
Better Health in Residents in Care Homes

Name:

I.D. No:

Better Health in Residents in Care Homes (BHiRCH)

Care Pathway for early illness detection and referral in care homes

STEP 1

STOP AND WATCH
(See attached Stop and Watch tool)

By: Care Assistant or Nurse
When: By the end of the shift
Why: Emphasises non-specific behavioural changes as indicators of illness and readily observed by care staff and families during routine care and visiting
Next step: Report to Nurse

STEP 2

PRIMARY ASSESSMENT

By: Nurse
When: Triggered by Step 1
Why: Continue to Step 3 if any test is positive. If all tests are negative, repeat Step 1 at 6-hour intervals

Check **respiratory rate** ▶▶ More than 22 per min = Test for **lower respiratory tract infection**

Rate:

Check for **lower urinary tract symptoms** ▶▶ Positive = Test for **urinary tract infection**

- increased frequency or urgency
- discomfort on passing urine
- lower abdominal discomfort/pain

Notes:

Check **temperature** ▶▶ More than 37.5°C = Test for **urinary tract or lower respiratory tract infection**

Temperature:

Check **blood pressure** ▶▶ MorSystolic BP (top figure) is lower than 110 = test for **dehydration**

BP:

Check **weight** ▶▶ 2kg decrease = Test for **dehydration**
2kg increase = Test for **deterioration of congestive heart failure**

Change in Weight:

BHiRCH
Better Health in Residents in Care Homes

Name:

I.D. No:

Care Pathway: Secondary Assessment

STEP 3

SECONDARY ASSESSMENT

By: Nurse
When: Secondary assessment of a specific condition is triggered by Primary Assessment
Next step: Continue to Step 4 if any test is positive. If all tests are negative, repeat Step 1 at 6-hour intervals

DEHYDRATION
Check **fluid intake** (less than 1 litre per day)
OR
Check **urine concentration**
OR
Check **urine output** (fluid or pads)
Check **skin turgor**
Check **BP**
→ **Dehydration**

Notes:

DETERIORATION OF CONGESTIVE HEART FAILURE:
Check **ankles/legs** → Increased swelling
Check **breathing** → Breathless
→ **Deterioration of Congestive Heart Failure**

Notes:

LOWER RESP. TRACT INFECTION:
Check for **breathlessness/noisy breathing**
OR
Check **Oxygen saturation**
Check **cough for change in phlegm, sound, frequency**
→ **Lower Respiratory Tract Infection**

Notes:

URINARY TRACT INFECTION:
Dip **urine** or **test pad** (NB potential for false positives for people with catheters) → Positive for nitrites
→ **Urinary Tract Infection**

Notes:

STEP 4

ACTION

Outcomes *Please tick all that apply*

Diagnosis ☐ Urinary tract infection ☐ Respiratory infection ☐ Congestive heart failure ☐ Dehydration ☐ Other ☐

Action ☐ Initiate treatment ☐ Monitor with Stop & Watch ☐ Monitor for specific symptoms ☐

Refer to primary care ☐ GP ☐ Community Nurse ☐ Emergency Services ☐ Telemedicine ☐ Other ☐

By: Nurse or Manager
When: Triggered by suspected diagnosis or other concerns raised at secondary assessment (Step 3)

Time to complete:

35 APPENDIX E STRCUTURED METHOD FOR COMMUNICATING WITH PRIMARY CARE (SBAR)

BHiRCH
Better Health in Residents in Care Homes

S

Situation:
I am (name) a Nurse at (Care Home name)
I am calling about (resident X)
I am calling because I am concerned that…..
(e.g. BP is low/high, temperature is XX, breathing has changed)

B

Background:
Resident X has been living with us since (X date)
They have been receiving (X medicines/X intervention)
Their last assessment indicated a risk of (X)
Resident (X)'s normal condition is… (e.g. alert/drowsy/confused, pain free)
Their condition has changed in the last (XX mins/hours/ days/weeks)

A

Assessment:
I think the problem is (X)
And I have…
(e.g. increased fluids, given analgesia)
OR
I am not sure what the problem is but resident (X) is deteriorating
OR
I don't know what's wrong but I'm really worried

R

Recommendation:
I need you to ….
See the patient (when?) / Consider prescribing (X drug) /
Make a referral to (X) / Advise me what to do (when? what next?)
AND
Is there anything I need to do in the meantime?
(e.g. stop the fluid / repeat the obs)

Ask receiver to repeat key information to ensure understanding

The SBAR tool originated from the US Navy and was adapted for use in healthcare by Dr M Leonard and colleagues from Kaiser Permanente, Colorado, USA

This version has been further adapted for use in care homes by the BHiRCH project